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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,646

07/15/2003

Simon Piers Robinson

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03/02/2007

John P. White
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,646	ROBINSON, SIMON PERS	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-75 is/are pending in the application.
- 4a) Of the above claim(s) 63-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/03, 1/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Upon reconsidering the Amendment filed on June 29, 2006 and telephonic interview the previous office action is vacated and the pending claims are considered for examination.

Applicants' amendment filed on June 29, 2006 presents new set of claims 56-75, canceling the claims 35-55. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The amendment cancelled claims 35-55 and present 56 as amended claim and claims 57-75 as new claims. Upon reconsidering the numbering of original claims it is noted that claim 56 was not present earlier, thus examiner treats the amended claim 56 as original claim 55 and renumbers the new claims as 56-74.

Misnumbered claims 56-75 have been renumbered 55-74.

Applicants' election Group I (which read on renumbered claims 55-61), with traverse am acknowledged. . The traversal is on the ground(s) that examining all the groups would not constitute a serious burden on the examiner, since the claims directed to a process of making the elected product and method of using the elected product. Applicants further argue that the claims recite a nucleic acid and corresponding amino acid and examining such claims would not be a burden on examiner. This is not found persuasive because of the following reasons: (I) a search for one group does not necessarily result in art related to another group that is, in the instant case, prior art search for method claims in Group I would not be co-extensive with prior art search for

method of increasing/ decreasing the level of PPO activity. Similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious, (ii) separate classification search is prima facie evidence of burden, (iii) the issues regarding each group of invention are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes. The MPEP states where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. In the instant context, the elected product is not yet determined as allowable. Hence the restriction is deemed proper and be maintained until the allowable subject matter is determined.

Status

2. Renumbered claims 55-61, are considered for examination. Renumbered claims 62-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

Information Disclosure Statement

3. The Information Disclosure Statement filed on July 15, 2003 and January 31, 2005 have been entered and considered.

Priority

4. This application filed on July 15, 2003 is a CON of 09/443,067 filed on 2/15/2000, PAT 6,627,794, which is a CIP of 08/976,22 filed on 1/21/1997.

Objection to the abstract of the specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract recites legal phraseology "said" in line 3 of the abstract. Correction is required.

Objection to the Drawings

6. The drawings are objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825. The instant application recites sequences that are not identified by SEQ ID No. (see Figures 1-15 reciting sequences with more than 10 nucleotides or more than 4 amino acids which are not represented by SEQ ID No.) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because as discussed above the Figures 1-15 are not represented by SEQ ID No. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office

action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance. Appropriate correction is required.

Claim interpretation

7. The claims recite 'comprising nucleotides in a nucleotide sequence set forth in SEQ ID No.', which read on any fragment of two or more nucleotides contained in SEQ ID No. 29 or 30.

Further claim 55 and 57 recite a nucleotide that encodes a copper-binding site of amino acid set forth in SEQ ID No. 30. The phrase "a nucleotide sequences set forth in SEQ ID No. 29 or 30" is interpreted as a nucleotide sequence encompassing two or more nucleotides fully complementary within said SEQ ID No. Thus the following rejection is based on a nucleic acid molecule encompassing at least two or more nucleotides set for the in said SEQ ID No. and any fragment encoding a copper binding site of an amino acid sequence of SEQ ID No. 30.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 55, 57-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al. (Plant Mol Biol., 21(6), page 1035-51, 1993).

Newman et al. teach a nucleic acid molecule encoding polyphenol oxidase polypeptide (PPO) of claims 56, 58-62, wherein Boss et al. disclose that the nucleotide sequence encompassing two or more nucleotides of SEQ ID No. 29 a nucleotide sequence that encodes

copper binding site of amino acid sequence of SEQ ID No. 30 (see alignment from protein database, and page 1041-1044, Fig. 2-3). A nucleotide sequence that encodes a copper-binding site (sequence alignment indicating copper-binding site A having absolute homology to the SEQ ID No. 30).

With reference to the instant claims 58-61, Newman et al. also disclose expression vector and the target organism in which the PPO gene is expressed. (see page 1037, col. 2, paragraph 3).

Thus the disclosure of Newman et al. meets the limitations in the instant claims.

B. Claims 55, 57-61 are rejected under 35 U.S.C. 102(a) as being anticipated by Boss et al. (Plant Mol Biol., 27(2), page 429-433, January 1995).

Boss et al. teach a nucleic acid molecule encoding polyphenol oxidase polypeptide (PPO) of claims 56, 58-62, wherein Boss et al. disclose that the nucleotide sequence encompassing two or more nucleotides of SEQ ID No. 29 a nucleotide sequence that encodes a copper binding site of amino acid sequence of SEQ ID No. 30 (see alignment from protein database, and page 430, col. 2, Fig. 1). A nucleotide sequence that encodes a copper-binding site (sequence alignment indicating copper-binding site A having absolute homology to the SEQ ID No. 30).

With reference to the instant claims 58-61, Boss et al. also disclose expression vector and the target organism in which the PPO gene is expressed (see page 430, col. 1, line 2-10, paragraph 1).

Thus the disclosure of Boss et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-61 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a genus of fragments of nucleotide sequence of SEQ ID No. 29 and 30 that encodes polyphenoloxidase and/ or a copper binding site of said SEQ ID No.. This large genus is represented in the specification by the named SEQ ID No. 29 and 30. Thus, applicant has express possession of only one species in a genus which, comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) With regard to a nucleotide sequence that encodes a copper-binding site, it is insufficient to demonstrate the identity of copper-binding site of a PPO polypeptide binding function in all these fragments where no structural information regarding where in the sequence the copper-binding site resides. Further no information is given regarding a methodology to determine such common elements or attributes. Further, there is no description of fragments.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No: 29-30 which include fragments for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to

practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the amino acid sequence of the disclosed SEQ ID No 30 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description, which would demonstrate conception or written description of any fragments or with the disclosed SEQ ID No. retaining correlative function in the claimed product.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU 2/20/07
PRIMARY EXAMINER